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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,766	03/15/2002	Wylie W. Vale JR.	D6390	4077

7590

04/08/2004

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/099,766

Applicant(s)

VALE ET AL.

Examiner

Sheridan K Snedden

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 15, 19-22, 25, 26, 30, 31, 35-45, 49, 50, 54-57, 60, 61, 65 and 66 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 35, 36, 39-40, 43-45, 49-50 is/are rejected.
- 7) ☒ Claim(s) 2-10, 15, 19-22, 25, 26, 30-31, 37, 38, 54-57, 60, 61, 65 and 66 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 11-14,16-18,23,24,27-29,32-34,46-48,51-53,58,59,62-64 and 67-77.

DETAILED ACTION

1. Applicant's election of invention I, claims 1-10, 15, 19-22, 25-26, 30-31, 35-45, 49-50, 54-57, 60-61, and 65-66 is acknowledged. Claims 11-14, 16-18, 23-24, 27-29, 32-34, 46-48, 51-53, 58, 59, 62-64, and 67-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper filed 9 January 2004. Claims 1-10, 15, 19-22, 25-26, 30-31, 35-45, 49-50, 54-57, 60-61, and 65-66 are under examination.

Claim Objections

2. Claim 31 is objected to because of the following informalities: claim 29 is dependent of non-elected claim 29. Appropriate correction is required.

3. Claims 2-10, 15, 19-22, 25-26, 30, 37, 38, 54-57, 60-61, and 65-66 is objected to because of the following informalities: that are directed to allowable subject matter, however, they are dependent of rejected claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1653

Claim 49 is indefinite as the complete phrase "selected from the group consisting of" is not used.

Claim Rejections - 35 USC § 102-103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 35, 36, 39, 44-45, 49-50 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hsu *et al.* (US 2002/0082409 A1).

Hsu *et al.* teach stresscopins peptide of SEQ ID NO : 6 that shares 100% identity with the human urocortin III protein of SEQ ID NO: 3 (regarding claims 1, 35, 36,). The protein or SEQ ID NO : 6 of Hsu *et al.* is described as the mature protein and differs from the current protein by the presence of two additional amino acids at the N-terminus.

Hsu *et al.* teach fragments of a stresscopin peptide where deletions at the amino terminus of peptides having binding affinity for CRH-receptors have the effect of turning an agonist peptide into an antagonist, by retaining the receptor binding activity, but deleting the activation activity. Such deletions generally extend from residue 1 through 10 of the peptide, and may further delete additionally amino acids at residues 11, 12 or more (see section [0022], regarding claims 44-45). Additionally, substitutions are taught (section [0023]), however, the specific substitutions of claims 37, 38, 54 are not expressly taught.

Hsu *et al.* teach that various groups may be introduced into the peptide during synthesis or during expression, which allow for linking to other molecules or to a surface. Thus carboxyl groups can be used for forming amides or esters, amino groups for forming amides, and the like (section [0027], regarding claim 39, 49-50). Thus, the reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1, 35, 36, 39-40, 43-45, 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu *et al.* (US 2002/0082409 A1).

Hsu *et al.* teach stresscopins peptide of SEQ ID NO : 6 that shares 100% identity with the human urocortin III protein of SEQ ID NO: 3 (regarding claims 1, 35, 36,). The protein or SEQ ID NO : 6 of Hsu *et al.* is described as the mature protein and differs from the current protein by the presence of two additional amino acids at the N-terminus.

Hsu *et al.* teach fragments of a stresscopin peptide where deletions at the amino terminus of peptides having binding affinity for CRH-receptors have the effect of turning an agonist peptide into an antagonist, by retaining the receptor binding activity, but deleting the activation activity. Such deletions generally extend from residue 1 through 10 of the peptide, and may further delete additionally amino acids at residues 11, 12 or more (see section [0022], regarding

Art Unit: 1653

claims 44-45). Additionally, substitutions are taught (section [0023]), however, the specific substitutions of claims 37, 38, 54 are not expressly taught.

Hsu *et al.* teach that various groups may be introduced into the peptide during synthesis or during expression, which allow for linking to other molecules or to a surface. Thus carboxyl groups can be used for forming amides or esters, amino groups for forming amides, and the like (section [0027], regarding claim 39, 49-50).

Hsu *et al.* teach stresscopin peptides that have been modified using ordinary molecular biological techniques and synthetic chemistry so as to improve their resistance to proteolytic degradation or to optimize solubility properties or to render them more suitable as a therapeutic agent. Analogs of such polypeptides include those containing residues other than naturally occurring L-amino acids, e.g. D-amino acids or non-naturally occurring synthetic amino acids (see section [0025]; regarding claim 40).

Hsu *et al.* teach that the stresscopin peptides may be labeled with radioisotopes to directly or indirectly provide a detectable signal for use in a binding assay, one or more of the molecules may be joined to a label (see section [0035]; regarding claim 43).

Hsu *et al.* does not expressly teach the use of D-iodotyrosine, for example or 125I radioisotope. However, given the suggestions of Hsu *et al.*, a person of ordinary skill in the art would have been expected success in using these common agents in the teachings of Hsu *et al.* Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Art Unit: 1653

Conclusion

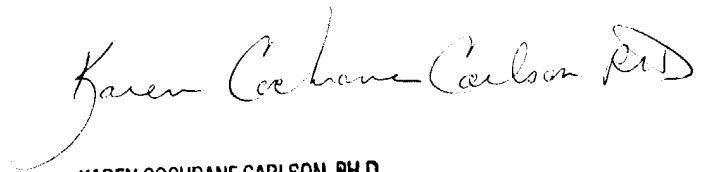
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
March 23, 2004

SKS



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER